



Partners Human Research Committee  
Partners Human Research Office  
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## Application: Notification of IRB Approval/Activation

Protocol #: 2008-P-000762/1; MGH

Date: 04/25/2008

To: Stephen Thomas, MD, MPH  
Emergency Service  
EOO Suite 3B

From: Fred Syllien *Oliver O'Neill for F.S.*  
PHS Research Management  
116 Huntington Ave Suite 1002

Title of Protocol: Descriptive Analysis of Late-Term Pregnant Patients Undergoing Critical Care Transport  
Version Date: 04/16/2008  
Sponsor: Internal Funding  
IRB Review Type: Expedited  
Minimal Risk: 45 CFR46.110 and 21 CFR56.110  
Expedited Category/ies: (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).  
IRB Approval Date: 04/21/2008  
Approval Effective Date: 04/25/2008  
IRB Expiration Date: 04/21/2009

This Project has been reviewed and approved by the MGH IRB, Assurance # FWA00003136. During the review of this Project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

**NOTES: The following documents have been reviewed and approved by the IRB: Research Limited to the Use of Health/Medical Records Application.**

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project in accordance with the IRB's policy on adverse event reporting.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.
4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.